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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,536	10/03/2003	Nobuaki Hanaoka	11333/28	3505

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EXAMINER	
FIELD, TAMMY K	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/678,536	**Applicant(s)** HANAOKA ET AL.	
	Examiner Tammy K. Field	**Art Unit** 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/03/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-9 are drawn to a method for detecting a malaria parasite, classified in class 436, subclass 546.

   II. Claims 10-12 are drawn to an apparatus for automatically detecting a malaria parasite, classified in class 435, subclass 291.

   III. Claims 13-22 are drawn to a reagent kit for detecting a malaria parasite, classified in class 435, subclass 7.32.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to analyze particles in a urine sample.

3. Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product or kit may be used to isolate malaria and extract malarial DNA.

4. The compositions of II and III are distinct from each other as claimed because they have different components (chamber, cytometer and control unit versus packaging materials), and have different preambles. As such, the compositions are distinct each from other.

5. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification and in the absence of restriction would place an undue burden on the examiner, restriction for examination purposes as indicated is proper.

6. A telephone call with Mr. Gregory Zayia on behalf of Mr. Tadashi Horie on March 31, 2004 resulted in a provisional election made without traverse to prosecute the invention of Group I, claims 1-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Claims 1-9 are presently under examination.

Priority

9. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted however, since the Office has not received an English translation of the Japanese application 2002-292612, the priority date of October 3, 2003 will be used for purposes of prior art.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Information Disclosure Statement

10. The information disclosure statement(s) filed October 3, 2003 has been considered. An initialed copy is enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims and bounds of the claimed subject matter. The claims are indefinite in the recitation of "wherein a zone" (claim 8) and "within a range" and "within the range" (Claim 9) because it is unclear from the specification what applicant intends. Clarification is required in order to overcome this rejection.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito-Ito, A. *et al.* 2001. (Parasitol. Internat. 50: 249-257).

The claims are drawn to methods for detecting a malaria parasite comprising releasing the malaria parasite, staining, detecting, and distinguishing the parasite wherein the specimen is treated with a first hemolytic agent, more specifically a nonionic surfactant and treated specimen is further treated with a second hemolytic agent, more specifically an anionic surfactant that does not damage the malaria parasite. Subsequent claims are drawn to introducing the stained sample into a flow cytometer, detecting and distinguishing the malaria parasite comprising scattering light intensity and fluorescent light intensity, preparing a two dimensional distribution diagram, and counting a number of cells of the parasite.

Saito-Ito, A. *et al.* teach a method for detecting a malaria parasite from blood supplemented with EDTA (inherently a nonionic first surfactant) comprising releasing the parasite erythrocyte suspension with or without parasites by treating with a hemolysing and staining solution, *i.e.* dodecyl methyl ammonium chloride and acridine orange, respectively, at pH 9 (inherently an anionic second surfactant) at Materials and Methods, pages 250-251. Saito-Ito, A. *et al.* further teach using flow cytometric analysis of the treated erythrocyte suspensions using the hemolysing and staining solution described supra. Two-dimensional scattergrams of green fluorescence (GF) (inherently fluorescent light intensity information) and forward low-angle light scatter (FSC) (inherently scattering light intensity information) of parasite-infected erythrocyte suspension (See Fig. 1a) with comparison of uninfected erythrocyte suspensions (see Fig. 1b) at Results, page 252. Saito-Ito, A. *et al.* also teach a schematic scattergram based on optical information obtained distinguishing areas of freed parasites' ring forms (r), late trophozoites (lt), schizonts (s), and merozoites (m), *i.e.* inherently the treatment of erythrocyte suspensions does not damage the parasite, at page 254 (see Fig. 4e).

13. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over van Vianen, P.H. *et al.* 1993. (Cytometry 14: 276-280).

The claims are drawn to methods for detecting a malaria parasite comprising releasing the malaria parasite, staining, detecting, and distinguishing the parasite wherein the specimen is treated with a first hemolytic agent, more specifically a nonionic surfactant and treated specimen is further treated with a second hemolytic agent, more specifically an anionic surfactant that does not damage the malaria parasite. Subsequent claims are drawn to introducing the stained sample into a flow cytometer, detecting and distinguishing the malaria parasite comprising scattering light intensity and fluorescent light intensity, preparing a two dimensional distribution diagram, and counting a number of cells of the parasite.

van Vianen, P.H. *et al.* teach an automated method for the detection of malaria parasites in blood samples using flow cytometry of erythrocyte treatments using a FACS Lysing Solution wherein this treatment ruptures red blood cells releasing malaria parasites at Materials and Methods, paragraph 1, page 277. van Vianen, P.H. *et al.* further teach prior to analysis lysing solution was removed and replaced with staining solution containing Hoechst 33258 in PBS. van Vianen, P.H. *et al.* also teach each sample containing mainly white blood cells and possibly released free parasites in 5,000 events were analyzed, identified, and selected by setting a gate in a two-dimensional dot-plot of forward angle light scatter (inherently scattering light intensity information) and blue (Hoechst) fluorescence (inherently fluorescent light intensity information) compared with data from a positive control sample at Materials and Methods, paragraph 3, page 277 (also see Fig. 1). Furthermore, van Vianen, P.H. *et al.* teach that the prior art method using flow cytometry allows for the detection and quantification of parasites in human material using various dilutions of malarial parasites at Results, pages 278, paragraph 2 (also see Fig. 2).

In the alternative, the limitations such as in Claims 3-4, wherein the method comprises a first nonionic surfactant and second anionic surfactant are viewed as limitations of optimizing experimental parameters. Thus, while van Vianen, P.H. *et al.* does not teach these limitations, their teachings indicate that the methods of the prior art are objective, fast, can be highly automated, and demonstrate that flow cytometry allows reproducible detection of 50 parasites per microliter of human blood which is ~0.0001% parasitemia (assuming 5 X 10^6 RBC/µl) at Discussion, pages 278-279, paragraphs 1-2, and 3. Additionally, the critically of using a first nonionic surfactant and second anionic surfactant instead of a FACS Lysing Solution of the prior art has not been established and further appears to be an obvious or analogous variant.

Thus, van Vianen, P.H. *et al.* anticipates or, in the alternative makes obvious the instantly claimed invention.

14. Since the office does not have the facilities for examining and comparing applicants' detection methods with the methods disclosed in the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed methods and the methods of the prior art (*i.e.* that the methods of the prior art does not possess the same material structural and functional characteristics of the claimed methods). See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitsgerald er al., 205 USPQ 594.

Status of the Claims

15. No claims allowed.

Conclusion

16. The prior art of record and not relied upon is considered pertinent to applicant's disclosure:

a. Pattanapanyasat, K. *et al.* 1993. Two-color flow cytometric analysis of intraerythrocytic malaria parasite DNA and surface membrane-associated antigen in erythrocytes infected with Plasmodium falciparum. Cytometry 14: 449-454 (teach a method applying two-color flow cytometric analysis of malaria DNA using immunofluorescence and saponin in detergent treated erythrocytes).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856. The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov./. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tammy K. Field
April 28, 2004

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